

AUG - 6 1997

Ms. Sonia Rodriguez
VP of Marketing and Regulatory Affairs
Mason Vitamins, Inc.
5105 N.W. 159th Street
Miami Lakes, Florida 33014-6370

Dear Ms. Rodriguez:

This is in response to your letter of July 30, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your product, L-Glutamine 500MG.

An important Amino Acid.
Helps lessen craving for alcohol consumption.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, that it "helps lessen craving for alcohol consumption," suggests that it is intended to treat or prevent a symptom of disease, namely alcoholism. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Florida District Office, Office of Compliance, HFR-SE240
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

975-0163

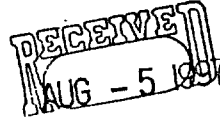
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The Vitamin Marketing Experts

July 30, 1997

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204



Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement L-GLUTAMINE 500 MG.

L-GLUTAMINE 500 MG will be first marketed with these statements of nutritional support on August 15, 1997. The statements of nutritional support are as follows:

An important Amino Acid.
Helps lessen craving for alcohol consumption.

Very truly yours,

Mason Vitamins, Inc.

Sonia Rodriguez
VP of Marketing & Regulatory Affairs

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